April 27, 2009

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To interested persons,

Attached is a comparative report concerning two mechanical circulatory support technologies: ventricular assist devices and direct mechanical ventricular actuation, which analyzes their effects and abilities to alleviate the widespread issue of heart failure. The information contained in this report may be of particular interest to someone directly or indirectly affected by heart failure.

A Ventricular assist device (VAD) is one type of cardiac assist device technology aimed to replace some function of the failing heart. A VAD can be targeted for the right ventricle, left ventricle, or both ventricles to mimic the natural pumping nature of the heart. Most VADs incorporate the use of cannula, or tubing, that allows blood to travel from the appropriate ventricle to the aorta (left ventricular assist device) or pulmonary artery (right ventricular assist device).

Direct mechanical ventricular actuation (DMVA) is another technology that provides circulatory support for the failing heart. Similar to the VADs, the DMVA support devices mimic the natural pulsing action of the heart, allowing for appropriate blood flow. Unlike the VADs, DMVA devices are non-blood contacting, meaning they do not utilize cannula that carry the blood from one part of the heart to another. Instead, the DMVA devices act directly on the outside of the heart, fitting over the heart's surface like a glove.

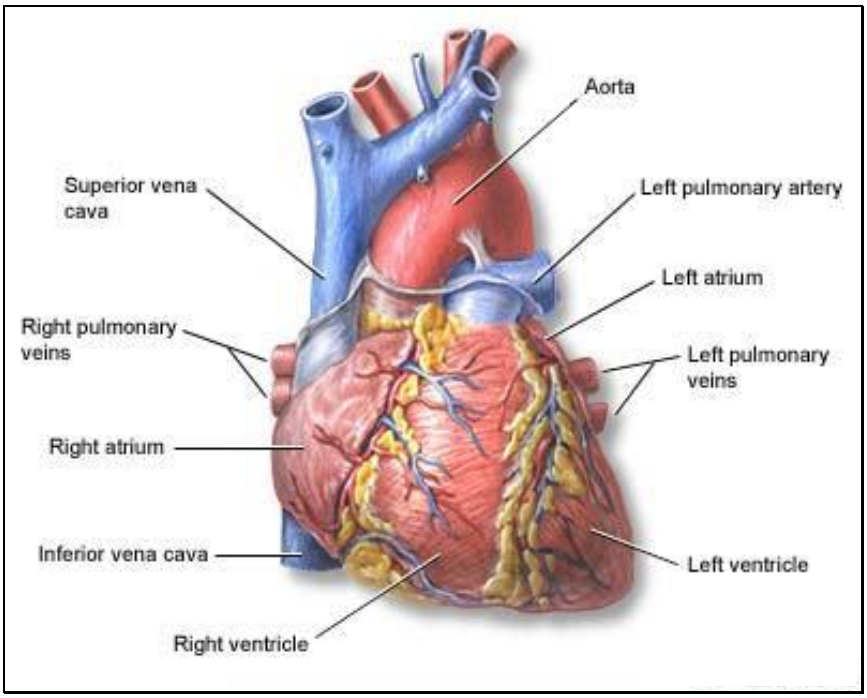
In this report, I intend to weigh the advantages and disadvantages of using either the ventricular assist device technology or the direct mechanical ventricular actuation device technology to aid the failing heart, as applied to their effects under certain circumstances.

I hope that you find the following report clear, informative, and helpful in your understanding of these two technologies and their effect on the treatment of heart failure.

Sincerely,

Keith Troche

Comparing the Use of Two Mechanical Circulatory Support Systems in Treatment of Heart Failure



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1. Summary

Ventricular Assist Devices and Direct Mechanical Ventricular Actuation are two technologies that have the potential to save the lives of many individuals affected by heart failure. While both treatment systems can be classified as mechanical circulatory support systems, the specific methods of ventricular augmentation differ greatly. As such, each system has its own unique set of advantages and disadvantages.

The Ventricular Assist Devices (VADs), although costly and susceptible to surgical and thromboembolic risks, provide patients with a formidable option that includes lifestyle benefits. The VADs are designed to be highly mobile allowing patients to continue living a relatively "normal" life. The downsides to VADs can be attributed to their use of blood-contacting cannula that participate in blood transport, which necessitate invasive surgery and are highly prone to blood clot formation. Current studies with VAD systems are focusing on developing a more biocompatible material which will greatly reduce these risk factors.

The DMVA technology, while still under development, may significantly reduce the cost requirements as well as the safety risks commonly associated with VADs. By acting directly on the outside of the heart rather than within the heart, DMVA has the advantages of a simple implantation procedure in addition to the elimination of the blood clotting risk. A major disadvantage of the treatment system is the confinement of the patient to a hospital/clinical setting, due to its dependence on a large pneumatic drive system. Further testing and experimentation on human subjects must still be performed using this technology.

1.1 Heart Failure: Epidemiology and Facts

Heart failure, by definition, refers to any condition that lessens the productivity of the myocardium, or the heart muscle (See Appendix I for a brief overview of basic heart physiology). More specifically, congestive heart failure, which refers to a low cardiac output by the heart, can be treated by a variety of options including the administration of pharmacological agents, surgery, and the use of cardiac assist devices.

Heart failure is a major public health issue in the United States, and its incidence is only increasing with the aging U.S. population. Roughly 5 million people in the United States currently suffer from heart failure, resulting in over 300,000 deaths per year (NHLBI, 2007). These numbers easily make heart failure the number one cause of death in the U.S., encouraging researchers to find new ways to combat this widespread issue.

Heart failure is the cause of 11 million office visits and over 3.5 million hospital visits in the U.S. alone, resulting in $23 billion spent annually on treatment for these patients (Murali). Even with the advent of new and improved treatment techniques, these numbers continue to rise each year without signs of slowing down. As these numbers suggest, not only is the issue of heart failure taking a toll on the health of Americans, but it also has damaging economic ramifications.

1.2 Why Use Mechanical Circulatory Support (MCS) Devices over Alternative Treatments?

There are several methods currently used to treat patients with heart failure, unfortunately there are major limitations and risks associated with each of the available methods. Examples of treatment systems that are only transient in nature include drug administration and defibrillator therapy (Deng). While these systems can provide a safe and immediate fix to the failing heart, these effects are only temporary and are not effective once the heart reaches more advanced stages of heart failure.

Heart transplantation has become a well-established technique in the treatment of heart failure, but it does not satisfy the demands of major public health issue. The shortage of healthy hearts available for transplant is a major limitation in the treatment of heart failure. Less than 5% of those in need of a donor heart receive one, and those who do have a five-year survival rate of approximately 65% (Wheeldon, 203). With the long waiting lists attached to receiving a heart transplant, many healthy patients ultimately suffer setbacks or sudden trauma that eliminates their eligibility to receive a donor heart. Physicians want to give the donor hearts to recipients with the highest predicted survival rate in order to make best use of this gift; the problem is that with so many patients waiting for their opportunity, many perfectly suitable candidates naturally deteriorate and lose their eligibility for a donor heart.

The inadequacy of the techniques mentioned as well as the discrepancy between the number of available donor hearts and those recipients awaiting one has led to extensive research concerning mechanical circulatory support systems. In short, mechanical circulatory support systems employ devices engineered to directly alter or

improve heart function by augmenting myocardium function. The following investigation will analyze and compare two mechanical circulatory support systems: ventricular assist devices (VADs) and direct mechanical ventricular actuation (DMVA) devices.

1.3 Overview of Ventricular Assist Devices

The VAD system aims to replace certain functions of the failing heart through the incorporation of cannula, or tubing, to transport blood. There are several variations of VAD systems; they can be targeted for the right ventricle, left ventricle, or both ventricles to mimic the natural pumping nature of the heart. Although there are many variations, all VAD systems utilize a small, internal pump that moves the blood from the inflow valve, through the device, toward the outflow valve. An example of an LVAD (left ventricular assist device) is the Thoratec HeartMate® XVE, as shown in Figure 1, which provides the energy needed to pump blood from the left ventricle to the rest of the body.

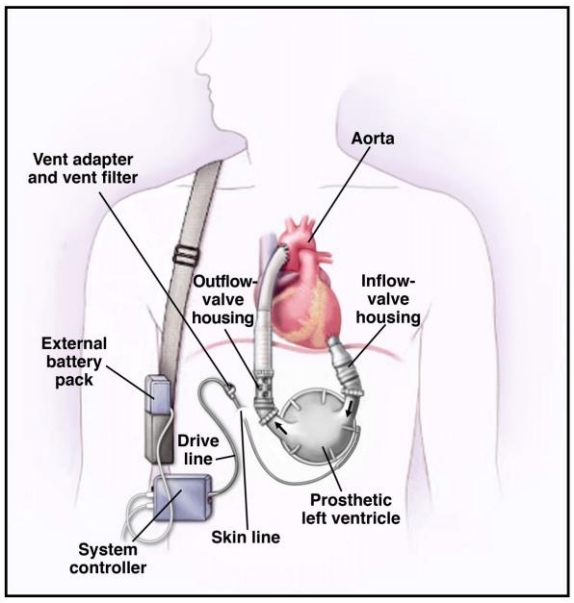

Figure 1: The Thoratec HeartMate® XVE showing the basic internal components.

1.4 Overview of Direct Mechanical Ventricular Actuation

Direct mechanical ventricular actuation (DMVA) is another technology that provides circulatory support for the failing heart. Similar to the VADs, the DMVA support devices mimic the natural pulsing action of the heart, allowing for appropriate blood flow. Unlike the VADs, DMVA devices are non-blood contacting, which means they do not utilize cannula to carry the blood from one part of the heart to another. Instead, the DMVA devices act directly on the outside of the heart (as can be seen in Figure 2), fitting over the heart's surface like a glove. It is also important to note that the DMVA technology provides bi-ventricular support, augmenting the function of both ventricles.

DMVA technology utilizes two external lines from the body: one to a vacuum and another to a pneumatic drive system. The vacuum line, connected at the apex of the cup, ensures that the heart fits snuggly in the device, so as to protect against injury. The pneumatic drive line, powered by an external mechanical piston, is responsible for the actual contraction and relaxation of the cup, which in turn contracts the heart.

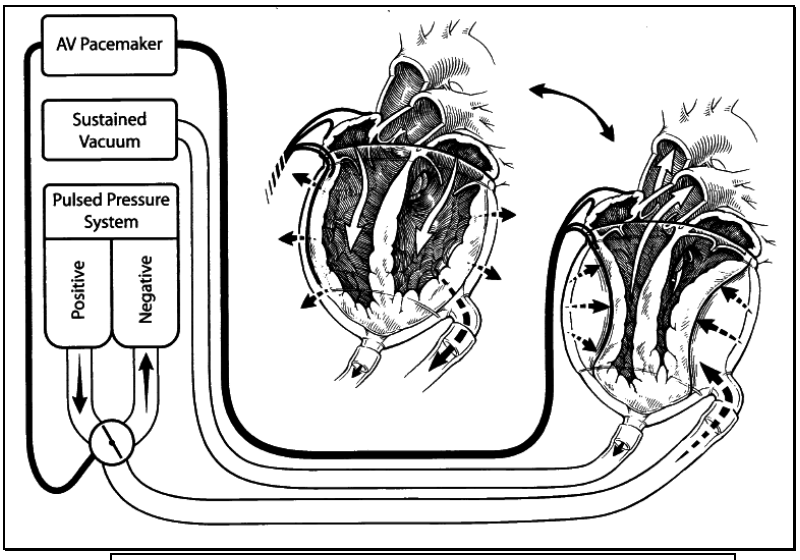

Figure 2: DMVA support device showing pumping action.

It should also be noted that unlike the VADs, there are currently no FDA-approved DMVA devices targeted for human use.

While both of these mechanisms are classified as bridge-to-transplant devices—meaning their use is intended to merely give the patient more time to potentially find a donor heart—improvements in design may one day lead to a permanent replacement of heart function.

2. Safety and Efficacy of Design

2.1 Surgical Installation

The method of surgical installation of the mechanical support device is a very critical consideration when choosing one of these two technologies, as many complications can arise during implantation. The VADs and DMVA devices employ varying strategies that each has advantages and disadvantages.

VAD

Due to the use of blood-contacting cannula, VAD implantation is a more complicated and invasive procedure than that of DMVA devices.

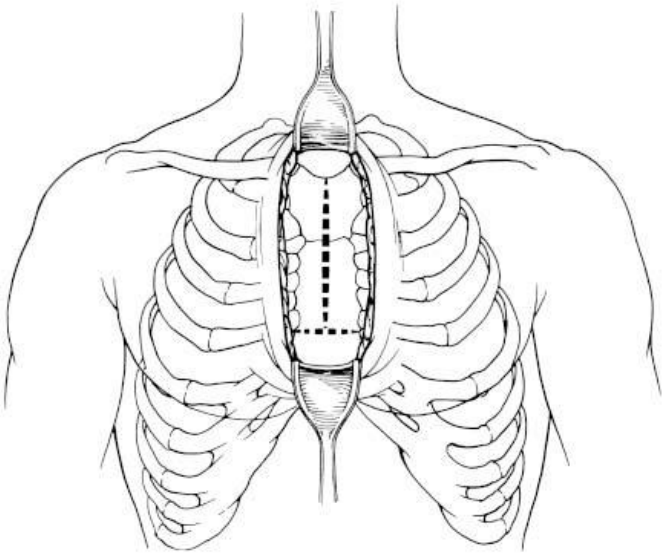

Figure 3: A schematic of the median sternotomy utilized for implantation.

In order to adequately expose the heart to install a VAD system, a median sternotomy must often first be performed on the patient (Hunt). The median sternotomy is a procedure in which an incision is made down the center of the patient's sternum, which is then essentially "cracked" open. The opening is maintained by use of retractors, which are tools physically holding the chest open. While this procedure allows full exposure of all surfaces of the heart, improving the visibility of the area for the doctor, this comes with an array of potential side effects. Complications of wound infection, nerve damage from the spine to the arm (brachial plexus palsy), extreme postoperative pain, pulmonary dysfunction, and disfiguring (poor cosmesis) are all potential complications of the procedure (Mongero, 142).

Even more potentially dangerous than the median sternotomy is the cardiopulmonary bypass that must be performed on most VAD patients which bring further considerations to light. Because the VAD system actually re-directs the blood flow through the heart and the circulatory system, upon implantation of a VAD the function of the heart and lungs has to essentially be "shut off" for some time. Without the cardiopulmonary bypass the heart would continue to pump, leading to a large blood loss upon the incision to incorporate the VAD. Through additional cannula, a cardiopulmonary bypass mechanically circulates and oxygenates the blood while bypassing the heart and lungs. In some patients incorporation of this machine can lead to an inflammatory response that can result in end-organ damage (damage in organs linked to the circulatory system), seriously compromising the health of the patient (Mongero, 143). Also, attachment of the aorta to the cannula through cross-clamping can increase the chance of blood clot formation potentially resulting in a stroke, a complication that

will soon be addressed. In addition, the attachment of the actual device cannula to the heart can result in further damage. Although doctors are highly skilled in performing this procedure despite all of these factors, even the best of doctors cannot foresee every possible complication.

DMVA

The implantation of the DMVA system is advantageous in that it is both a simple procedure, avoiding many of the complications associated with the VADs, and allows for a rapid installation.

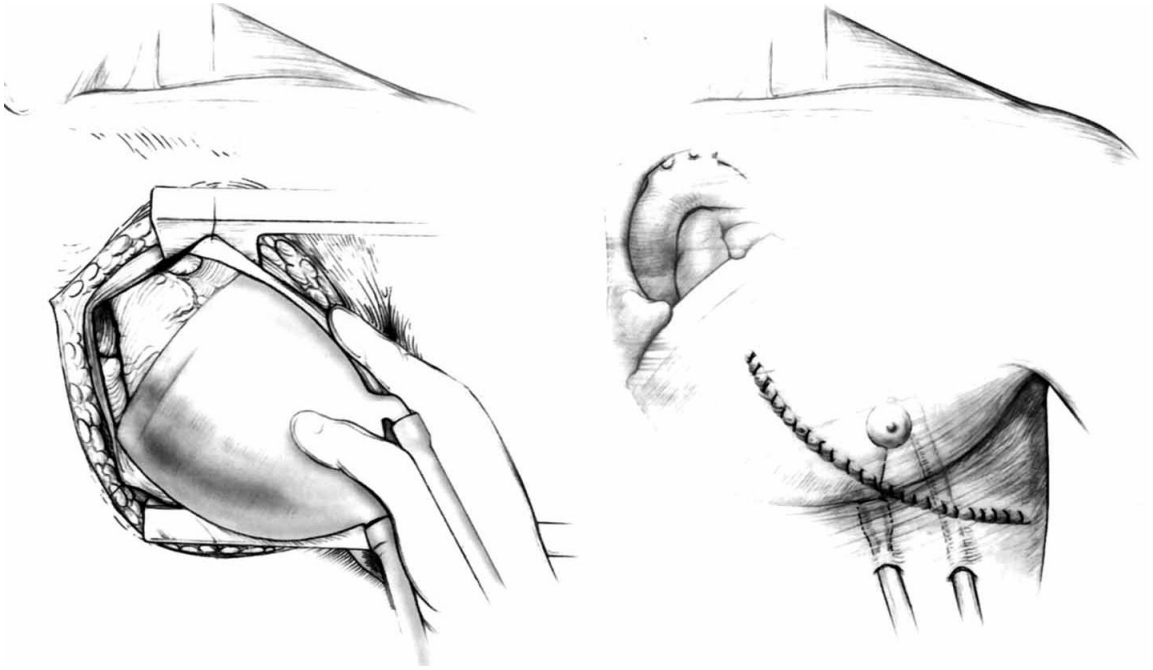

Figure 4: A schematic of the incorporation of a DMVA system through a side thoracotmy.

In order to install the DMVA system, a small left anterior, sixth intercostal space thoracotomy must be performed on the patient (Lowe). Rather than completely opening the chest cavity, an incision is made toward the side of the chest and retractors are used to spread the ribs apart, providing access to the heart. This less invasive procedure as well

as the smaller opening necessary to access the heart significantly reduces the risks associated with DMVA systems as compared to VADs. Also, a cardiopulmonary bypass is not necessary for DMVA implantation, completely eliminating that risk factor altogether.

Whereas the typical VAD can take 45 minutes or more to install onto a heart, a DMVA support device can be implanted in just three minutes (Dhuri). Following exposure via a thoracotomy, the DMVA cup can be slipped over the heart, at the precise angle, in just a few seconds resulting in two chief advantages. The first is that due to the short, and relatively simple procedure for DMVA application, specially trained doctors will not be required to apply such a device. Whereas a VAD can be a complicated system that many physicians would not be comfortable working with, DMVA support requires no special skills. Second, due to the fast acting nature of the DMVA system, support for the failing heart can begin almost immediately. Rather than sitting idle within a patient's chest, the heart will quickly experience augmentation, restoring the natural pumping function.

2.2 Thromboembolism and Device Complications

Thromboembolism is a major issue for all devices that come into contact with the blood, and are a major source of failure for mechanical circulatory support systems. Thromboembolism is not only an important concern because of its deadly consequences, but also because of the additional complications it can lead or contribute to. (See Appendix for additional details regarding Thromboembolism.)

VAD

The VAD technology is often highly susceptible to thrombus formation through its use of blood contacting cannula transporting the blood. A major issue with the VAD system is that a material that is completely biocompatible with blood has yet to be discovered. The inability to make a strong yet distendable (flexible) material that matches the composition of the heart leads to elevated flow stresses in the non-physiologic geometries of the artificial material, promoting the build-up of blood platelets on the inside surface (Wakhloo, 24). Rather than traveling through the heart smoothly, the blood can begin to stick to the side of the artificial material. Once it is of a significant size, this build-up of platelets will form what is commonly known as a blood clot, or a thrombus. After some time this thrombus can become detached, affecting important areas such as the brain, depriving them of oxygen delivery. The interior of VAD systems were commonly constructed from a smooth artificial polymer, which was frequently associated with such thromboembolic complications. Recently VAD systems have commonly incorporated the use of textured polyurethane and titanium surfaces, which has been relatively successful in reducing accumulation of platelet cells (Padera).

Anticoagulation drugs, used to reduce the incidence of thrombus formation, can lead to an increased risk of infection and hemorrhage in the patient. Because of the use of non-biocompatible material in association with blood, patients using most VAD systems must take anticoagulation drugs in order to reduce the blood clotting factors within the blood. Anticoagulation drugs, such as the widely used Heparin are blood thinners which lower the viscosity of the blood. Thinning the blood in this way greatly increases the risks of both rapid blood loss (hemorrhage) upon damage to the vessels, as

well as infection within the body, due to a reduction in the efficacy of wound healing (Padera). As such, use of anticoagulation drugs is to be avoided if at all possible.

DMVA

DMVA technology is enormously advantageous in that it avoids the issue of thrombus formation altogether. By acting on the outside of the heart, there are no artificial materials associated with blood transport. This design eliminates both the potential build-up of platelets within the device as well as the need to take anticoagulation drugs.

3. Lifestyle and Convenience

Although the primary purpose of mechanical circulatory support devices is to sustain the life of a patient suffering from heart failure, issues concerning the quality of the patient's life must also be taken into account.

VAD

Many VAD technologies are small, wearable systems that allow for limited mobility of patient. As designs have improved, most VADs now include rechargeable batteries that directly power the internal pumping mechanism via wiring that goes through the skin (see Figure 1). The average life of these rechargeable batteries typically ranges from 3-5 hours—giving patients adequate time to perform many of the activities they enjoyed prior to the surgery. There is also the incorporation of a system controller in most VAD technologies that allows patients to adjust the pumping rate of the device based on their current activity level (Mechanical). While it is understandably not recommended for VAD patients to engage in heavy physical activity, this gives the patients some freedom to move around freely and participate in activities such as

walking. Most VAD systems are small enough that patients can carry the system around with them using a belt and shoulder straps, supporting the external battery and system controller. This design allows patients to comfortably move about, allowing them to carry on living a relatively "normal" life.

DMVA

A major disadvantage of the DMVA technology is that it confines the patient to a hospital/clinical setting, greatly restricting the patient's mobility. As mentioned previously, DMVA systems are powered by a pneumatic drive system, which is essentially a large mechanical piston positioned near the patient. Because this drive system is critical to the function of DMVA technology, a patient under DMVA support cannot move but a few steps away from the system.

4. Current Products on the Market

A factor that largely differentiates the VADs from the DMVA support devices is the number of FDA-approved devices of each technology on the market today and their prevalence in hospitals.

VAD

There are five major VADs currently available for public use— The Thoratec HeartMate® XVE**,** The Thoratec® VAD**,** The Novacor® Left Ventricular Assist System**,** the ABIOMED® BVS 5000 Biventricular Support System, and the ABIOMED® AB5000™ Circulatory Support System—and several other currently under clinical trials (Mechanical). The current products provide a wide range of functionality in terms of intended use, pumping mechanism, size, reliable support time, and materials used. To illustrate this point a comparison can be made between the Thoratec® VAD and the the

Novacor® Left Ventricular Assist System**.** Thoratec® VAD which has the ability to provide left, right, or bi-ventricular support can only supply short term support due to its existence outside of the body. In contrast, while the Novacor® Left Ventricular Assist System only has the ability to support the left ventricle, it can be utilized for long term support because of its inclusion within the body.

DMVA

Currently there are no FDA-approved DMVA support devices and few developers are building these systems. However, one company called Biophan is making strides in developing the DMVA technology. Biophan is a company whose primary focus is on the development of MRI-compatible biomedical solutions has recently consolidated MYOTECH, LLC, the developers responsible for the MYO-VAD™ technology (Dhuri). The MYO-VAD™ DMVA technology is making advancements in both its functionality and clinical trials. Extensive clinical trials using animals have shown positive results with successful cardiac support from the DMVA devices sustaining the lives of the animals for extended periods of time. In addition, researchers at Wright State University are lending their efforts to assist in the development of the technology. While few human trials have been studied and tested using the technology, Biophan is certainly moving in that direction.

5. Cost Considerations

An important consideration in the treatment of heart failure is the cost a patient will incur over the course of a treatment strategy. While patients understandably desire the most effective treatment possible when dealing with heart failure, they must be able to endure the chosen treatment strategy financially. The Randomized Evaluation of

Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) is a trial, supported by the National Heart, Lung, and Blood Institute, that compares transplantation and VADs at a financial level in the treatment of heart failure (Rose). Due to the fact that there are currently no DMVA devices on the market, there are no official numbers as to the financial considerations of the treatment system, but relative estimates can be made.

VAD

Cost data from the REMATCH trial does not show a major discrepancy in the estimated cost of transplantation versus using VAD technology. A median estimate for VAD support of roughly $250,000—with a $65,000 device cost included—was made, compared to a total transplantation estimate of about $205,000, according to a 2003 report (Wheeldon). These cost estimates are based on the agents administered to the patient, the surgical techniques necessary for implantation, and hospital costs. It is important to note that roughly 75% of these costs are due to the hospitalization fees incurred throughout the whole procedure.

DMVA

Although REMATCH and other clinical trials have not considered the use of DMVA systems, it is estimated a significant cost reduction will accompany use of these systems. Rather than a complex device made of many components as in a VAD, the DMVA support system is essentially a polymer cup, making it much easier to produce. Once a mold is properly designed for a specific heart size, the costs of producing more DMVA heart cups is little more than the polymer used to form it. The polyester fiber and polyurethane polymer used in the construction of the cup is known for its high flexibility

and low production cost. The only additional equipment needed is a data acquisition system (computer) and a pneumatic drive device. Also, as mentioned previously, this simple yet effective design allows for more ease of installation, leading to lower procedure costs.

6. Future Prospects and Potential

As technology continues to advance and our understanding of the bodily processes heightens, researchers will continue to modify and improve both device systems in the near future.

VAD

There are several additional VAD systems currently under development and progress is being made in finding non-thrombogenic material to work with. One particular example that is showing promise is the Thoratec HeartMate® II LVAS (HeartMate). The HeartMate II, currently under phase II trials, exhibits several advantageous features: small size—$1/8^{th}$ the size of current products allows this VAD to be used in a wide range of patients including children, automatic speed control mode—that automatically paces the heart based on activity level, thromboresistance—requires only a low dose anticoagulation regimen, and increased durability. Many other VADs under development are similarly instituting these advantageous features, and are beginning to gain more public interest. Additionally, much time and effort is currently being expended in the search for a more biocompatible material from which to make the VAD systems. While the use of textured polyurethane and titanium surfaces is showing encouraging results, further research is necessary.

DMVA

The DMVA technology is quickly gaining a more widespread acceptance within the medical community and is demonstrating that it may be a safe and effective treatment of heart failure in the near future. Clinical trials currently being performed are demonstrating the many advantages of DMVA support as previously discussed, and more and more human testing is now underway. Researchers are currently looking at ways to reduce the size of the pneumatic drive system, possibly giving DMVA patients some degree of mobility in the future.

7. Conclusion

Ultimately both Ventricular Assist Devices and Direct Mechanical Ventricular Actuation exhibit their advantages and disadvantages in the treatment of heart failure. The VADs, which currently suffer from an invasive procedure upon implantation, heightened medical costs, and thromboembolism-related risks, have the unique advantages of availability and increased lifestyle accommodations. On the other hand, the DMVA support devices, which have the drawbacks of severely limiting the mobility of the patient as well as not having FDA-approved products on the market, may lessen the financial burden which affected families must endure and lower the safety risks associated with such devices. It is up to the patients and their families to decide which course of action is better for them. The fundamental goal with these support systems is to improve both the health and livelihood of the affected individuals, giving them the opportunity to continue living a fruitful and rewarding life. Attached is a summary table consolidating all of the relevant factors to be considered when comparing the two technologies.

8. Appendix I

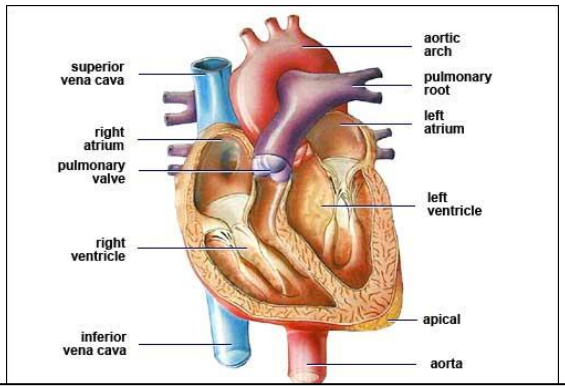

Figure 5: The heart showing the four chambers.

The heart essentially serves as a pump that moves blood throughout the circulation, delivering nutrients and removing wastes from the organs and the rest of the body (Katz). The heart is composed of four separate chambers: the right and left atria, as well as the right and left ventricles (Figure 5). The atria serve to essentially collect the blood and pump it to the ventricles, which then deliver either oxygenated blood to the body (left ventricle) or deoxygenated blood to the lungs (right ventricle). A diagram of the complete circulatory system can be seen in Figure 6.

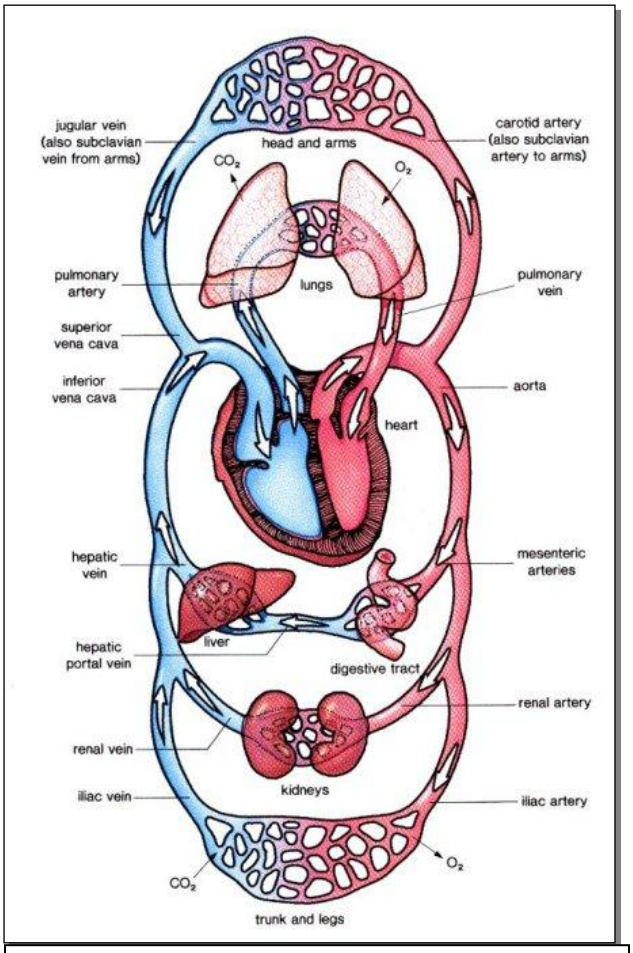

Figure 6: The circulatory system and the direction of oxygen transport.

The function of the ventricle is to apply pressure to a volume of fluid (blood) by producing wall tension. As seen in the circulatory system, this tension produces pressure which is the primary determinant of oxygen consumption by the heart.

There are two important phases that the heart continually repeats: diastole and systole. The diastolic phase refers to when the chambers of the heart relax and fill, while the systolic phase refers to the occurrence of contraction of the ventricles. As diagrammed in Figure 7, a deficiency in either of these actions can have detrimental effects upon the heart and will subsequently lead to heart failure. It is also important to note that the heart contains three layers: the endocardium—inner layer, the myocardium—muscular tissue of the heart, and the epicardium—outer layer. Damage to the myocardium is a common cause of heart failure, as the heart will no longer have the strength to properly relax and contract.

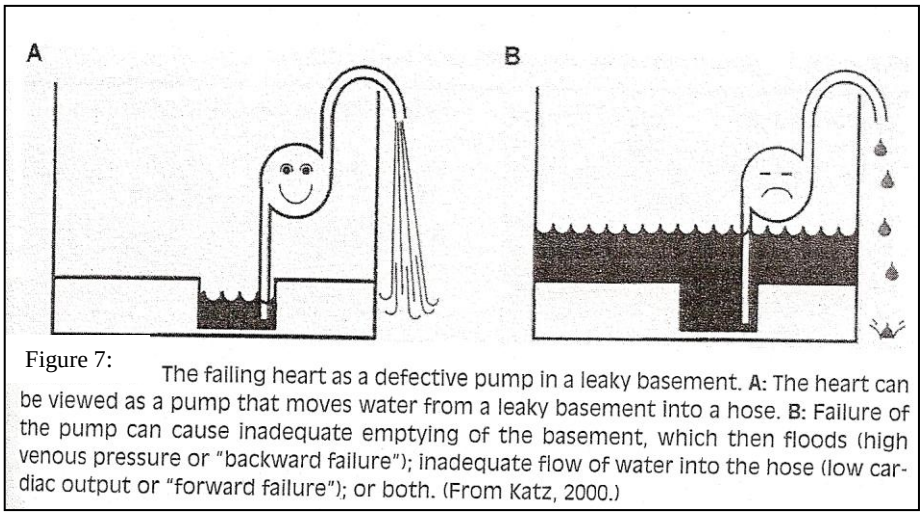

Figure 7: The failing heart as a defective pump in a leaky basement. A: The heart can be viewed as a pump that moves water from a leaky basement into a hose. B: Failure of the pump can cause inadequate emptying of the basement, which then floods (high venous pressure or "backward failure"); inadequate flow of water into the hose (low cardiac output or "forward failure"); or both. (From Katz, 2000.)

Thromboembolism refers to two specific phenomena: thrombosis and embolism. Thrombosis refers to the formation of a blood clot within a vessel, obstructing blood flow. The formation of a blood clot naturally occurs in order to prevent blood loss from a

damaged vessel. When there is too much clotting, an embolism in which the object breaks free from the blocking point to act further downstream in the body. Embolism is a major concern because it can then lead to ischemia (a restriction in the blood supply) and eventually a stroke.

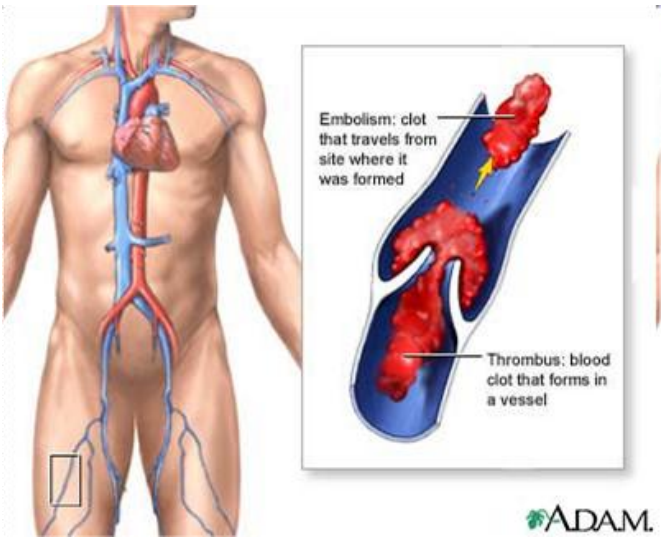

Figure 8: Thrombus and Embolus formation within a vessel.

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Summary of the Advantages of Each Treatment System		
	Ventricular Assist Devices	**Direct Mechanical Ventricular Actuation Devices**
Thromboembolism Safety and Device Complications	• The cannula of VADs are often highly susceptible to the formation of blood clots • A material that is completely biocompatible with blood has yet to be discovered • Most VADs require the use of anticoagulation drugs to avoid this issue—increases incidence of infection	• Does not employ the use of cannula • No requirement for anticoagulation drugs
Surgical Installation Safety	• Most VADs require a cardiopulmonary bypass—increases risk • Requires a median sternotomy—extremely invasive procedure • Cannula have to be anastomosed to the heart	• Requires a 6^{th} intercostal space thoracotomy—less invasive • Simple application—the device slides easily over the heart • Necessitates a much faster procedure
Lifestyle and Convenience	• Small size allows the patient limited mobility • Most VADs are powered by rechargeable batteries lasting 5-6 hours • System controller allows manual pacing of the heart	• Coupling of the vacuum and pneumatic drive system to the device • Limited mobility—patient confined to hospital/clinical setting
Cost Considerations	• Average cost of considering hospitalization time, surgical implantation, and device cost ranges from $225,000-$300,000	• No official numbers available, but is expected to be far more financially feasible • Device costs will be little more than the polymer used in its construction
Future Potential	• Several new VAD systems are currently under development • Progress is being made finding more suitable biocompatible materials for device construction	• DMVAs are nearing FDA-approval and are gaining acceptance in the medical community • Research is being performed to reduce the size of the pneumatic drive system.